

Amendments to the Specification:

Please replace the paragraph from Column 1, line 56 – column 2, line 10 with the following amended paragraph:

--The scalpel of the invention provides practitioners with a scalpel that has the feel and weighting of a traditional reusable scalpel with the benefits of a fresh blade and a shield that substantially prevents inadvertent access to the sharp blade and that is intuitively movable from the distal position where the blade is protected to the proximal position to expose the blade. The shield of the scalpel of the invention is releasable from the proximal position by the practitioner's direct downward pressure on a digital activation section. The shield includes ergonomic grips to direct the practitioner's hand to a position for mounting the cartridge on the handle where it is unlikely that there will be inadvertent release of the shield for movement from the [proximal] distal position where the blade is protected to the [distal] proximal position where the blade is exposed. The replaceable cartridge that includes the blade allows the personnel charged with arming and disarming the scalpel to handle only a protected blade and substantially prevents operating room personnel from being exposed to the blade during set-ups and transfers of equipment during procedures and substantially prevents exposures to used blades during disarming and clean-up procedures. --

Please replace the paragraph at Column 2, lines 44-45 with the following:

--FIG. 6 shows a perspective view of an alternative embodiment of the blade holder with the blade attached; --

Please replace the paragraph at column 2, lines 60-62 with the following:

--FIG. 13 is a perspective view in [part] partial section of an alternative handle embodiment having a button for locking the shield in position over the blade;--

Please replace the paragraph at column 3, lines 5-7 with the following:

--FIG. 18 is a partial perspective view of the cartridge being mounted to the handle [of] to form the scalpel of the invention;--

Please replace the paragraph at column 3, lines 19-20 with the following:

--FIG. 23 is a partial exploded perspective view showing the removal of the cartridge from the handle; [and]--

Please replace the paragraph at column 3, lines 21-22 with the following:

--FIG. 24 is a perspective view of the blade holder of the invention[.];--

Please replace the paragraph at column 4, lines 29-40 with the following:

--Turning in detail to the FIGS. 1-15, the surgical scalpel 10 is first shown in FIG. 1 with the blade 12 secured to the blade holder 20. The scalpel 10 is gripped by the [hand] handle 50 which has a preferably contoured elongated grip portion 52. As is shown in FIGS. 2a and 2b, adjacent the front end of the blade holder 20 are two tabs 22 and 24 for securing the blade 12 to the blade holder 20 by inter locking with respective openings on the blade 12. Adjacent the back end of the blade holder 20 is the attachment slot 26 shown as a female end connection. Channels 28 are positioned longitudinally on opposite sides of the blade holder 20 along a channel section 30 of the blade holder 20.--

Please replace the paragraph at column 4, lines 41-47 with the following:

--A hook 32 is cantilevered from the back end of the blade holder 20. The hook 32 can resiliently flex upwardly and downwardly to engage the handle 50. The cantilevered end of the hook 32 has an inclined aft surface 34 and a protrusion 36 which is adapted to engage a complementary shaped [grooved 50] groove 60 on the handle 50 when the blade holder 20 mates with the handle 50.--

Please replace the paragraph at column 5, lines 1-12 with the following:

--The sleeve 70 preferably has a digit engaging portion 78 adjacent to the arch 74 having a series of ribs forming a thumb rest. [t]The digit engaging portion 78 improves the surgeon's "feel" for the sleeve 70 when the sleeve 70 slides along the guide channels 28 and 54 by hand or thumb pressure. FIG. 5a shows an assembled scalpel 10 with the sleeve 70 in a forward position to cover [of sheath] the blade 12. The forward movement of the sleeve 70 is guided by the guide flanges 72 that travel along the guide channels 28

and 54. With the sleeve 70 moved fully forward, the radiused surface 76 contacts the hook 32 to stop additional forward movement.--

Please replace the paragraph at column 8, lines 30-53 with the following:

--Blade holder 320 may be formed from thermoplastic materials such as polypropylene, polyethylene, polycarbonate, polysulfone, polyacetal, polyamide and the like. Shield 338 may be formed from thermoplastic materials such as polypropylene, polyethylene, polycarbonate, polyacetal, and polyamide and the like. For particular applications shield 338 may be formed from a substantially transparent material. Handle 312 may be formed from a material such as machined metal, formed powdered metal and thermoplastic or thermoset materials. In the preferred application, shield 338 and blade holder 320 are formed from thermoplastic materials such as polypropylene and polycarbonate with a stainless steel blade to form the single-use cartridge 318. [flandle] Handle 312 preferably is formed from machined metal or formed powdered metal to provide a durable reusable device that provides the practitioners with the same "feel" and "heft" that they are accustomed to with the current reusable handles and with removable single-use bare blades. Handle 312 preferably has a surface treatment, here illustrated as knurling 313, to improve the practitioner's ability to securely grip the scalpel. Other surface treatments including roughening, grooving, checkering and the like may be preferred for particular applications and are considered within the scope of the invention.--

Please replace the paragraph at column 9, line 56 – column 10, line 20:

--Shield 430 includes a cantilever 432 with a digital activation section 434 projecting upwardly from a top surface 435 of the shield. When cartridge 418 is mounted on handle 412, a practitioner may apply digital pressure to digital activation section 434 sufficient to downwardly deflect cantilever 432 and release shield 430 for movement between the proximal position and the distal position. Scalpel 410 has a groove 436 that extends from the blade holder 420 from a distal terminus 438 onto handle 412 to a proximal terminus 440 on one side of the scalpel. Preferably, scalpel 410 has a groove 436 on each of a first side 437 and a second side 439, each with distal termina 438 on blade holder 420 and proximal termina 440 on handle 412. Cantilever 432 further

includes at least one boss 442, preferably two bosses 442 disposed to engage each of grooves 436. Each termina of groove 436 is an upward enlargement disposed to engage bosses 442 when shield 430 is positioned in either the proximal or distal positions. When bosses 442 are engaged in the termina, shield 430 is substantially prevented from movement. When the practitioner applies sufficient downward force to digital application section 434 to deflect cantilever 432, bosses 442 are no longer engaged with the upward enlargements at the [termina] terminal thereby allowing the practitioner to selectively move shield 430 between the proximal and distal positions as desired. Bosses 442 track in grooves 436 to stabilize shield 430 during the movement between positions, and when a terminus is reached, bosses 442 preferably serve to provide a practitioner perceptible "snap" as the bosses engage the enlargement and allow cantilever 432 to return to the rest position to assist the practitioner in recognition of the completion of desired movement of the shield.--

Please replace the paragraph at column 10, line 46 – column 11, line 13:

--Shield 430 preferably includes a deflectable tab 450, best seen in FIGS. 27, 28, 32 and 32A, with an inwardly projecting lug 452 that is disposed to engage a seat 454 in blade holder 420. Seat 454 is best seen in FIGS. 26, 33 and 35B. During initial assembly of cartridge 418, preferred blade 426 with an aperture 456 is fixedly attached to an outward protuberance 458 on blade holder 420 by fitting aperture 456 over protuberance 458 so that blade 426 is substantially rigid with respect to blade holder 420. Suitable fixed attachments of blade 426 to blade holder 420 are formed by heat staking the projection onto the aperture, adhesive bonding or the like. Shield 430 has a proximal end 460 and a distal end 462. The assembly then includes substantially axially aligning proximal end 460 of the shield with distal end 424 of the blade holder and proximally advancing the shield onto the blade holder to form cartridge as shown in FIG. 25. As is best seen in FIGS. 35A, 35B, 35C and 35D grooves 436 have a first depth "a" between distal termina 438 on the blade holder and a shoulder 464 and a second depth "b" between [distal termina 438] the shoulder 464 and distal end 424 of the blade holder. Second depth "b" is less than first depth "a" thereby to form a shoulder 464 at the intersection of depths "a" and "b". As shield 430 is proximally advanced onto blade

holder 420, bosses 442 engage grooves 436 at second depth "b" and deflect. As shield 430 is further proximally advanced onto the blade holder, bosses 442 engage deeper first depth "a" at distal termina 438 and are substantially prevented from returning to second depth "b" region by shoulder 464 thereby substantially preventing distal movement of shield 430 with respect to blade holder 420. Tab 450 with inwardly projecting lug 452 is disposed to engage seat 454 in blade holder 420 when bosses 442 are in distal termina 438, thus substantially preventing further movement of shield 430 with respect to blade holder 420 until cartridge 418 is mounted onto handle 412.--

Please replace the paragraph at column 11, lines 14-28:

--Preferably, shield 430 is substantially prevented from movement with respect to blade holder 420 during mounting of cartridge 418 onto handle 412 even if the practitioner unintentionally applies sufficient pressure to digital activation surface 434 to deflect cantilever 432. [Proximal end 414] Distal end 416 of handle 412 is preferably disposed to engage at least one of bosses 442 as cartridge 418 is proximally advanced onto handle 412 when cantilever 432 is deflected downwardly. Additionally if the practitioner were to inadvertently apply pressure to digit activation surface 434 after cartridge 418 is partially properly advanced onto handle 412, preferred handle 412 further includes a recess 466 disposed on a top surface 467 of handle 412 to engage at least one of bosses 442 to function as a false stop and substantially prevent further advancement of cartridge 418 onto handle 412.--

Please replace the paragraph at column 13, lines 21-55 with the following:

Shield 530 includes a first cantilever 532 with a digital activation section 534 projecting upwardly from a top surface 535 of the shield. When cartridge 518 is mounted on handle 512, a practitioner may apply digital pressure to digital activation section 534 sufficient to downwardly deflect cantilever 532 and release shield 530 for movement between the proximal position and the distal position. Scalpel 510 has a groove 536 that extends from the blade holder 520 from a distal terminus 538 onto handle 512 to a proximal terminus 540 on one side of the scalpel. Preferably, scalpel 510 has a groove 536 on each of a first side 537 and a second side 539, each with distal termina 538 on

blade holder 520 and proximal termina 540 on handle 512. Cantilever 532 further includes at least one boss 542, preferably two bosses 542, best seen in FIG. 39, disposed to engage each of grooves 536. Each termina of groove 536 is preferably an upward enlargement disposed to engage bosses 542 when shield 530 is positioned in either the proximal or distal positions. When bosses 542 are engaged in the termina, shield 530 is substantially prevented from movement. When the practitioner applies sufficient downward force to digital application section 534 to deflect cantilever 532, bosses 542 are no longer engaged with the upward enlargements at the termina, thereby allowing the practitioner to selectively move shield 530 between the proximal and distal positions as desired. Bosses 542 track in grooves 536 to stabilize shield 530 during the movement between positions, and when a terminus is reached, bosses 542 preferably serve to provide a practitioner perceptible "snap" as the bosses engage the enlargement and allow cantilever 432 to return to the rest position to assist the practitioner in recognition of the completion of desired movement of the shield. Preferably, termina 538 and 540 each include a roof portion 541 that substantially prevents boss 542 from upward disengagement from the termina. Adjacent to roof portion 541 are ramped end portions 541b which define the ends of the cut away portion 541a. Roof portion 541 defines the bottom of the cut away portion 541a.--

Please replace the paragraph at column 14, lines 1-33 with the following:

--In this embodiment, preferred first cantilever 532 extends distally from proximal end 560 of shield 530. Referring to FIGS. 40a and 40b, which are schematic representations of a portion of shield 430 of the embodiment shown in FIGS. 25-36c, and FIGS. 40c and d, that are schematic representations of a portion of shield 530 as illustrated in FIGS. 37-39, the reason for the preferred configuration of cantilever 532 is seen. In the embodiment of shield 430 with cantilever 432, if a practitioner inadvertently applies proximal force F_i to the [distal] digital application section 434 during the mounting of cartridge 418 onto handle 412, resultant moment M is seen in FIG. 40b with a concomitant resultant to move boss 432 downwardly from distal termina 438 thereby potentially, if the force is sufficient, inadvertently releasing shield 430 for proximal movement to expose blade 426. Referring now to FIGS. 40c and 40d, illustrating the

preferred configuration of cantilever 532, it is apparent that the application of the same proximal force F_i to digital application section 534 results in a concomitant resultant to move boss 532 upwardly in distal termina 538. Diagrams comparing these resultants are seen in FIGS. 40b and 40d. The upward resultant on boss 532 and the downward resultant on boss 432 are shown in FIGS. 40d and 40b respectively. The placement of the effective hinges H_{400} and H_{500} of the cantilevers 432 and 532 provide the direction of the resultant action on the bosses 432 and 532. When the preferred cantilever 532 configuration is coupled with the distal upward pitch of surface 590 and proximal upward pitch of surface 591 in distal upward termina 538 in the preferred scalpel 510, the probability of an inadvertent release of shield 530 for proximal movement during mounting of cartridge 518 onto handle 512 is substantially reduced.--

Please replace the paragraph at column 14, lines 46-52 with the following:

--In FIGS. 38b and 38c, a more preferred configuration for digital activation section 534a is illustrated. This more preferred configuration reduces any inadvertent force applied by the practitioner to cantilever 532 during mounting cartridge 518 to handle 512, while facilitating the [intention] intentional movement of shield 530 to the proximal position to expose blade 526 for its intended use.--

Please replace the paragraph on column 15, line 66 -- column 16, line 34 with the following:

--Cartridge 518 is releasably mounted to handle 512 by engaging a downward projection 580 on handle 512 with a pocket 582 on a flexible beam portion 584 that projects proximally from blade holder 520. To remove cartridge 518 from handle 512, cartridge 518 is distally advanced from handle 512. Preferably, shield 530 substantially surrounds blade holder 520 and substantially prevents inadvertent access to blade 526 when shield 530 is in the distal position. When shield 530 is proximal, blade 526 is exposed for use, bosses 542 are disposed in proximal termina 540 and shield 530 surrounds at least a portion of handle 512. Since shield 530 substantially surrounds at least a portion of the handle when it is in the proximal p position, beam 584 is substantially prevented from flexing downwardly to release projection 580 from pocket 582 by the shield, thus

substantially preventing cartridge 418 from being dismounted from handle 512 when the blade is exposed. Additionally, if a practitioner inadvertently applies distal force to attempt to move the shield to the distal position, the presence of bosses 542 in proximal termina 540 substantially prevent movement of shield 530 to the distal position. To move shield 530 to the distal position, the practitioner must apply sufficient force to the digital activation surface 534 to downwardly deflect cantilever 532 and release bosses 542 from the proximal termina 540. If a practitioner grasps shield 530 and attempts to remove cartridge 418 from handle 412 after shield 430 is released from the proximal position, but before shield 530 is fully seated in the distal position and blade 526 is substantially protected from inadvertent access, shield 530 substantially prevents the disengagement of pocket 582 from projection 580 until the shield is distally advanced to substantially protect blade 526 from inadvertent access. Then, as handle 512 is separated from cartridge 518, prong 578 is disengaged from tab 550 thereby allowing lug 552 to engage seat 554 and substantially prevent movement of shield 530 with respect to blade holder 520.--